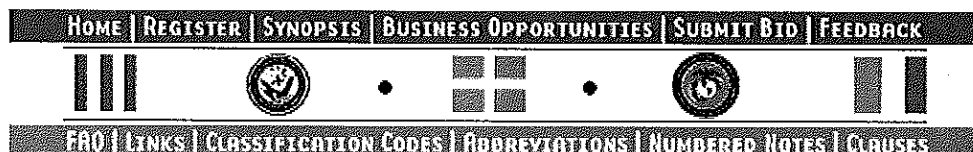


**Trading Partner/Order/Currency Information****Solicitation Number:** M20001-15-Q-0001**Synopsis:** [View Synopsis](#)**Trans. Purpose:** Original**Issue Date:** Request For Quote: Sep 02, 2015**Date/Time Reference**

| <u>Date Reference</u>                      | <u>Time Zone</u> | <u>Date Time Period</u> |
|--|------------------|-------------------------|
| Quote to be Received By: Tue, Sep 08, 2015 | Eastern Time     | 09:00 AM                |

**Contact Information****Entity Identifier:** Buying Party (Purchaser) USMC CHEMICAL BIOLOGICAL INCIDENT RESPONSE FORCE**DoD Identification:** Department of Defense Activity Address Code (DODAAC) M20364**Address 1:** 4th Marine Expeditionary Brigade (AT)**Address 2:** NSWC , 101 Strauss Avenue, Bldg. 901**City/State/Zip:** Indian Head, MD 20640**Administrative Communications Contact**

| <u>Contact Function</u>                     | <u>Communications Number</u>  |
|---|---|
| Buyer Name or Department: Randall Chatfield | Telephone: 301-744-2094   |
| Buyer Name or Department: Randall Chatfield | Electronic Mail: <a href="mailto:randall.chatfield@usmc.mil">randall.chatfield@usmc.mil</a> |
| Buyer Name or Department: Randall Chatfield | Facsimile: 301-744-2018   |

**Line Items****Line Item:** 0001**Quantity:** 2**Federal Supply Classification** U099**Download File:** [M20364/M2000115Q0001M20001-15-Q-0001 Performance Work Statement.docx](#)**Download File:** [M20364/M2000115Q0001M20001-15-Q-0001 RFQ Basic Combat Trauma Training.doc](#)**Download File:** [M20364/M2000115Q0001DOD-CONTRACTED MEDICAL TRAINING INVOLVING USE OF LIVE ANIMALS.pdf](#)**Line Item Product/Item Description****General Desc:** Basic Combat Trauma Training**Detail Desc:** [Please See Synopsis](#)



Synopsis Database

DETAIL



| COMBINED NOTICE  |  |
|--|--|
| Subject: U--Basic Combat Trauma Training   |  |
| Synopsis Date: Sep 02, 2015  |  |
| Contracting Office M20001 U.S. Marine Corps Forces Command (MARFORCOM) 1775 Forrestal<br>Address: Drive Norfolk, VA 23551  |  |
| NAICS Code: 611699 All Other Miscellaneous Schools and Instruction   |  |
| Classification Code: U - Education and Training Services   |  |
| Solicitation Number: M2000115Q0001   |  |
| Response Date: Sep 08, 2015  |  |
| Archive Date: Sep 23, 2015   |  |
| Contact Points: GySgt Chatfield, Randall 757-445-4290 GySgt Chatfield, Randall Phone: 757-445-4290 Fax: 757-444-9779 email: randall.chatfield@usmc.mil   |  |
| Set-Aside: Total Small Business  |  |
| <a href="#">View Solicitation</a>  |  |
| <p><b>Description:</b> 1) This is a combined synopsis/solicitation for commercial items prepared in accordance with the format in FAR Subpart 12.6, in conjunction with FAR 13, as applicable, and as supplemented with additional information included in this notice. This announcement constitutes the only solicitation; quotes are being requested and A WRITTEN SOLICITATION WILL NOT BE ISSUED.</p> <p>Solicitation number M20001-15-Q-0001 is being issued as a Request For Quotation (RFQ). This solicitation document and incorporated provisions and clauses are those in effect through Federal Acquisition Circular (FAC) 2005-81 and the Defense Federal Acquisition Supplement (DFARS).</p> <p>The North American Industry Classification System (NAICS) Code is 611699 and the small business size standard is 11.0 Mil. This acquisition is set-aside 100% for Small Businesses. Quotes received from concerns that are not a small business shall be considered nonresponsive and will be rejected.</p> <p>2) General Requirement: This RFQ is being issued for 2 separate Basic Combat Trauma Training Courses in accordance with the attached Performance Work Statement (PWS); one course to be conducted on 09-11 September 2015, and the other on 26-28 September 2015. Classroom portions of the training shall be conducted at the Government's training facility on Fort Story, Virginia Beach, VA; all other training shall be conducted at the contractor's facility, which must be located no more than 60 miles from Fort Story. Please see attached PWS for other special requirements/instructions regarding the training and facilities to be used.</p> <p>3) Contractor Qualification and Experience: The contractor shall comply with all current federal, state and local statutory and regulatory requirements, including MCCDC Combat Trauma Training With Live Tissue Policy Guidance.</p> <p>In accordance with MCCDC Combat Trauma Training With Live Tissue Policy Guidance, the contractor shall be currently certified in writing by the Headquarters, USMC Health Services (HQMCHS), to conduct the CTT/TTT at the level as described in this contract.</p> <p>PLEASE SEE ATTACHMENT TITLED DOD-CONTRACTED MEDICAL TRAINING INVOLVING USE OF LIVE ANIMALS FOR COMMERCIAL VENDOR REVIEW AND APPROVAL PROCESS</p> <p>4) Contractors responding to this announcement must provide the information contained in 52.212-3, Offeror Representations and Certifications—Commercial Items with their quote. The contractor should also provide its Commercial And Government Entity (CAGE) Code, Contractor Establishment Code (DUNS number) and Tax Identification Number (TIN). Contractors must be registered in the System for Award Management (SAM) to be eligible for any resulting awards (NO EXCEPTIONS). For information on registering with SAM, visit <a href="http://www.sam.gov">www.sam.gov</a>. Contractors are also required to be registered in Wide-Area Work Flow (WAWF); contractors can self-register for WAWF at <a href="https://wawf.eb.mil">https://wawf.eb.mil</a>.</p> <p>5) Quotations for this request may be submitted electronically to GySgt Randall Chatfield at <a href="mailto:randall.chatfield@usmc.mil">randall.chatfield@usmc.mil</a>; faxed to (757) 444-9779. Written, facsimile, or emailed quotes and required information must be received at this office on or before 08 September 2015, by 09:00 a.m. Eastern Standard Time.</p> |  |
| Place of Performance:  | Marine Corps Security Cooperation Group (MCSCG) 937 Atlantic Ave Fort Story, Virginia Beach, VA, 23451, US |

## Related Notices

Award Notice 09/15/2015 08:35 am





Synopsis Database

DETAIL



| AWARD NOTICE  |  |
|---|--|
| Subject: U--Basic Combat Trauma Training  |  |
| Synopsis Date: Sep 15, 2015   |  |
| Contracting Office M20001 COMMANDER U.S. MARINE CORPS FORCES ATLANTIC-<br>Address: CONTRACTING 1468 Ingram Street Norfolk, VA |  |
| NAICS Code: 611699 All Other Miscellaneous Schools and Instruction  |  |
| Classification Code: U - Education and Training Services  |  |
| Solicitation Number: M2000115Q0001  |  |
| Related Notice: COMBINED NOTICE   |  |
| Archive Date: Sep 23, 2015  |  |
| Contact Points: GySgt Chatfield, Randall 757-445-4290 randall.chatfield@usmc.mil  |  |
| Set-Aside: Total Small Business   |  |
| Contract Award<br>Number: M20001-15-F-0018  |  |
| Contract Award<br>Dollar Amount: \$88,200.00  |  |
| Contract Line<br>Item Number: 0001, 0002  |  |
| Contract Award Date: SEP 08, 2015   |  |
| Contractor: Assessment and Training Solutions Consulting Corporation  |  |





UNITED STATES MARINE CORPS  
MARINE CORPS INSTALLATIONS COMMAND  
3000 MARINE CORPS PENTAGON  
WASHINGTON, DC 20350-3000

IN REPLY REFER TO:

10570

G-3

JUN 13 2014

MARINE CORPS INSTALLATIONS COMMAND POLICY LETTER 4-14

From: Commander, Marine Corps Installations Command  
To: Distribution List

Subj: USE OF ANIMALS FOR TRAINING ON MARINE CORPS INSTALLATIONS

Ref: (a) OSD Memorandum "Location Recommendation for Live Animal Use Training" of 24 Oct 13  
(b) DoDI 3216.01  
(c) DoD Veterinary Services Advisory B-003  
(d) NAVMED P-117  
(e) BUMED 6280.1B  
(f) 7 USC § 2131-2159  
(g) MARADMIN 209/12  
(h) MCCDC Policy Memorandum of 1 Jul 11

Encl: (1) Approval Checklist

1. Situation. The use of live animals for training and educational purposes has provided our Corpsmen, Marines, and other first responders with valuable lifesaving skills on the battlefield. Commonly referred to as Combat Trauma Training (CTT) that includes Live Tissue Training (LTT), the experience and confidence gained by the use of the live animal model in training lifesaving procedures to our first responders has been successful. These training programs have proven to be a visceral learning experience for our warriors that deal with the most intense and tragic battlefield trauma.

2. Mission. To establish policy and procedures for the use of animals for training and/or educational purposes on Marine Corps installations.

3. Execution

a. Commander's Intent and Concept of Operations

(1) Commander's Intent. Reference (a) recommends all Department of Defense (DoD) conducted and DoD supported use of animals be restricted to military installations or host nation government installations in order to mitigate adverse public perception involving the use of animals.

(2) Concept of Operations. According to the guidelines established in references (b), (c), (d), and (e), Marine Corps Installations Command (MCICOM) does not meet DoD and Department of the Navy (DON) guidance necessary to ensure the health and safety of personnel conducting training with live animals.

b. Subordinate Element Missions

(1) MCICOM does not have veterinary staff to ensure all animal protocols are followed according to applicable laws, statutes, and regulations.

1

Subj: USE OF ANIMALS FOR TRAINING ON MARINE CORPS INSTALLATIONS

(2) LTT requires the use of controlled medications to ethically sedate animals. MCICOM does not possess the licensed personnel or facilities to prescribe, administer, store, audit, and monitor these medications in accordance with reference (d).

(3) The use of animals during LTT creates Regulated Medical Waste (RMW). For health and sanitation reasons, this waste is strictly controlled in accordance with reference (e). MCICOM does not possess the facilities, training, or standard operating procedures to properly dispose of RMW.

c. Policy. The use of animals for LTT on Marine Corps installations is prohibited. This policy also includes the use of live animals for subsistence training.

(1) This policy does not apply to:

(a) Activities conducted solely for the purpose of training animals or if the activity is conducted for the purpose of training personnel about animal care and handling as described in reference (b).

(b) Ceremonial, recreational, or working animals (e.g., military working dogs).

(c) The slaughter of game animals as a result of hunting, trapping, fishing, etc. as prescribed and authorized by federal and local regulations when the sole purpose of field slaughter is for human consumption of the animal for food and no training is involved. This is only applicable to personnel licensed/authorized by the commanding officers of Marine Corps installations to hunt/trap/game/fish live animals.

(2) Exemptions. Organizations requesting an exemption to this policy will submit a request to the respective Marine Corps installations regional commander for approval using the enclosed checklist (Enclosure 1).

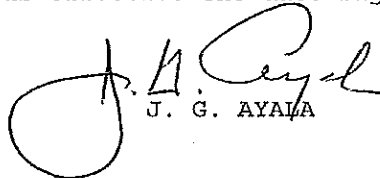
d. Alternate Training Sites. Reference (a) does not prohibit LTT or subsistence training from being conducted at a contractor-supported site off the Marine Corps installation that has been approved by the Commanding General, Training and Education Command and the Medical Officer of the Marine Corps nor does it preclude this type of training from being conducted at other service installations that meet all DoD and DON animal use guidelines.

4. Administration and Logistics. Recommendations concerning the content of this policy may be forwarded to the Assistant Chief of Staff, G-3/5/7.

5. Command and Signal

a. Command. This policy is applicable to all Marine Corps installations and tenant commands.

b. Signal. This policy is effective the date signed.

  
J. G. AYALA

DISTRIBUTION: C

## Approval Checklist for Use of Animals for Live Tissue/Subsistence Training Aboard Marine Corps Installations

| Item                                       | Requirement  | Veterinary Officer's Initials |
|--|--|-------------------------------|
| 1  | The training to be conducted cannot be accomplished using didactic, hands-on, simulators, or other alternatives to animal use.   |                               |
| 2  | This training is directed by the following: Formal Course POI<br>1. Formal Course POI: Y / N<br>2. Course Code or Title:<br>3. Service or Joint Training Directive:<br>4. Theater/Combatant Commander:   |                               |
| 3  | The lead instructor is experienced and certified in Advanced Medical Training (AMT) and will not be instructing on procedures that he/she is not authorized to perform on human patients.  |                               |
| 4  | All participants in the training are volunteers to include support staff.  |                               |
| 5  | The contractor's veterinarian or the unit Veterinarian shall be present during all aspects of training involving animals from procurement to disposal of animal waste.   |                               |
| 6  | Positive control measures shall be in place to prevent the use of photography, videography, or other means of recording the training.  |                               |
| 7  | Appropriate security is in place along the line of sight perimeter to prevent observation of the training.   |                               |
| 8  | The DoD Institutional Animal Care and Use Committee (IACUC) providing protocol oversight has been informed and has approved the training.  |                               |
| 9  | A Public Affairs plan has been established and the MCI PAO has been made aware of the scheduled training.  |                               |
| 10   | A Special Use Range Request has been submitted to and approved by the appropriate installation commander or his designated representative.   |                               |
| 11   | All animals used for training have been legally procured through approved suppliers licensed by the US Department of Agriculture (USDA).   |                               |
| 12   | The Unit Medical Office has validated that:<br>1. The Contracting Company veterinarian / unit veterinarian is present and that adequate veterinary care will be provided throughout the training.<br>2. Appropriate anesthesia and analgesia is provided to the animals to ensure the animals are pain-free.<br>3. Protocols approved by the IACUC are being followed.<br>4. Proper animal holding facilities are available<br>5. Animals receive proper food and water.<br>6. Measures to prevent non-anesthetized animals from seeing ongoing AMT are in place.<br>7. Proper animal handling procedures shall be observed. |                               |
| 13   | Disposal of Regulated Medical Waste (RMW) will be as follows:  |                               |
| Signature of Attending Veterinarian: _____ |  | Date: _____                   |
| Signature of Unit Medical Officer: _____   |  | Date: _____                   |
| Signature of Commanding Officer: _____     |  | Date: _____                   |

**Performance Work Statement (PWS)  
for  
Marine Corps Security Cooperation Group**

**1. Background**

1.1. The Marine Corps Security Cooperation Group (MCSCG) will be deploying teams of Marines throughout South America, Africa and Central Command area of operations. These Marines will train and advise foreign militaries. MCSCG requires these Marines to have advanced training in several fields to improve the team's ability to advise and train as well as force protection for themselves. These Marines will be required to have the capability and understanding combat casualty care to prepare for their missions. The MCSCG requires manpower support to further its ability to conduct training in selected tasks.

**2. Scope**

2.1. The MCSCG requires contractor developed curriculum for combat casualty care skill sets for Marines and Sailors deploying.

**3. General Facility and Accommodation Requirements**

3.1. All components of the training must be no further than 50 miles of each other.

**4. Tasks.**

4.1. The Contractor shall provide (1) Basic Combat Medic Course (BCM) for:

**CLIN 0001 – 38 students**

**CLIN 0002 – 12 students**

4.2. Didactic training shall include, but is not limited to: the requirements currently outlined in United States Marine Corps (USMC), Tactical Combat Casualty Care (TCCC), and Basic Medical Course (BMC). Changes to this training will be consistent with approved revisions to TCCC and BMC. Additional training may vary as the result of specific requests and requirements of the USMC unit being trained (i.e.: burns, blasts, head injuries, patient extrication, environmental emergencies).

4.3. Training shall include didactic instruction and practical hands-on training.

4.4. Instructor to student ratio shall not be less than 1:15 for group skills training. Practical exercises in patient assessment and live tissue training shall not be less than 1:4 instructors to student ratio.

4.5. Contractor shall have an internal evaluation system of both the course curriculum and the practical exercises.

4.6. Contractor shall provide all supplies and equipment necessary to execute the training requirements under this purchase order.

4.7. Hands-on based practical exercises shall be conducted to maximize learning and retention in the following topics with a minimum of 75% hands on training.

4.8. The contractor shall provide skills based practice and individual student evaluation for all items in the USMC individual medical kit, airway management, hemorrhage control, shock and fluid resuscitation, bandaging and splinting, needle thoracotomy, medical administration, parenteral IV's and IO's, and patient carries to ensure the students have an understanding of the material.

4.9. Contractor shall conduct medical product demonstrations of medical products (i.e.: homeostatic agents,

tourniquet and chest dressings).

4.10. Contractor shall conduct trauma scenarios based on the level of student training and experience as determined by Marine Corps Security Cooperation Group (MCSCG). The higher the level; the more complicated the scenario.

4.11. Contractor shall conduct three (3) evolutions of live tissue training consisting of one (1) table-top instruction evolution and two (2) scenario based evolutions. Students will be required to manage all injuries consistent with those outlined in TCCC, those seen in combat, and the approved protocols.

4.12. Each course shall include a Pre and Post-test on TCCC and a pass/fail rate will be provided to the Government representative.

4.13. Course completion certificates shall be issued to validate compliance with USMC TCCC training requirements.

4.14. Contractor shall provide the Basic Combat Trauma Kit for retention by students following the instruction.

## **5. Deliverables**

5.1. Contractor shall provide academic course materials for all courses to include course outline, student handouts, and evaluation/testing results and deliver them to the designated Government Representative.

| <b>Deliverable</b>                     | <b>Content</b>                                | <b>Due Date</b>                                |
|--|---|--|
| Course Outline                         | Course Schedule, times / dates.               | First working day prior to class start date.   |
| All required medical supplies          | Required medical supplies                     | First day of Combat medic course.              |
| Comprehensive After Action Assessment. | Assessment of the each student's performance. | Within 10 working days after the end of class. |

## **6. Government Responsibilities**

6.1. The Government will provide a classroom located at Fort Story, Virginia Beach for the conduct of all in classroom instruction.

## **7. Special Requirements**

7.1. Training areas shall be capable of supporting multiple trauma lanes and an animal containment area compliant with all United States Department of Agriculture (USDA), Animal Welfare Act 9 Code of Federal Regulations (CFR), Institutional Animal Care and Use Committee criteria.

7.2. In accordance with MCCDC Combat Trauma Training with Live Tissue Policy Guidance dated 1 July 2011, the contractor shall be certified in writing by the Headquarters, USMC Health Services (HQMC-HS), to conduct the Combat Trauma Training /Live Tissue Training at the level as described in this purchase order.

7.3. Contractor shall have all land permits and insurance coverage to support the legal conduct of this training at their facility; all local, state, and federal permits pertaining to live tissue training; adhere to all applicable regulations for disposal of animals, animal products, and other medical waste; and ensure all participants adhere to all local, state and federal regulations.



## **8. Acceptance**

8.1. Acceptance of the Contractors performance under this contract shall be at the discretion of the Government representative based on the terms and conditions of the contract.

## **9. Period of Performance**

9.1 Place and time of performance. The place of performance for work associated with this contract shall be at the Government location and at the contractor's facility.

The period of performance shall be as follows:

**CLIN 0001 – 09 September-11 September 2015**

Classroom Instruction September 9 and September 10, 2015. The Live Tissue portion will be on September 11, 2015.

**CLIN 0002 – 26 September-28 September 2015**

Classroom Instruction September 26 and September 27, 2015. The Live Tissue portion will be on September 28, 2015.

## DOD-CONTRACTED MEDICAL TRAINING INVOLVING USE OF LIVE ANIMALS COMMERICAL VENDOR REVIEW & APPROVAL PROCESS

This information paper provides guidance for prospective vendors, and secondarily for DoD contracting personnel, on Component specific submission, review, and approval processes for government contracting of medical training involving use of live animals, including requirements for obtaining "approved vendor" status. Any questions should be directed to the respective DoD Component Animal Use Oversight office.

*Prior to submission of a solicitation proposal, all prospective vendors desiring to bid on a government contract for medical training of DoD personnel, if involving use of live animals, must first be granted approval and included on the most current list of approved vendors, for each individual Component they plan to support. All DoD and Component specific requirements must be met in order to obtain initial "approved vendor" status. Upon obtaining initial approval, in order to maintain this status, per DoD Instruction 3216.01, compliance inspections are required to be completed annually thereafter.*

### 1. U.S. ARMY (Conventional Forces)

#### A. References

- (1) Animal Welfare Act, Title 7, U.S. Code, Sections 2131-2158, as amended, and Animal Welfare Act Regulations, Title 9, Code of Federal Regulations, Animals and Animal Products, chapter 1, subchapter A, Animal Welfare, Parts 1-4, as amended.
- (2) DoD Instruction 3216.01, Use of Animals in DoD Programs, 13 Sep 2010
- (3) DoD Instruction 1322.24, Medical Readiness Training, 6 Oct 2011
- (4) Army Regulation 40-33, The Care and Use of Laboratory Animals in DoD Programs, 16 Feb 2005 (*currently undergoing major revision*)
- (5) DoD Component Animal Use Management Plan for the U.S. Army, 18 Apr 2012
- (6) AR 350-1, Army Training and Leader Development, 18 Dec 2009/RAR 4 Aug 2011
- (7) HQDA EXORD 096-09, Mandatory Pre-Deployment Trauma Training (PDTT) For Specified Medical Personnel, 18 Dec 2006, with modifications
- (8) HQDA ALARACT 173-2013, Army Medical Readiness Training Involving Use of Live Animals, 13 Jul 2013
- (9) AMEDDC&S Policy Memo 13-016, Receipt and Review of Commercial Vendor Programs of Instruction (POI), 6 Jun 2013

#### B. Instructions for Vendors -- Submission, Review, and Approval Process

(1) Program of Instruction (POI) Review: See reference (9) above. Contact the Army Medical Department Center & School (AMEDDC&S), G3/5/7 Operations, Fort Sam Houston, TX, via e-mail, at [usarmy.jbsa.medcom-ameddcs.list.ops@mail.mil](mailto:usarmy.jbsa.medcom-ameddcs.list.ops@mail.mil), to request POI submission requirements. The POI, along with any required support documents, should be submitted per AMEDDC&S guidance and NOT sent directly to the above e-mail address. Upon receipt, requests will be logged and forwarded to the Academy of Health Sciences (AHS), Office of the Dean, for review by the appropriate subject-matter-expert (SME). Once POI review has been completed, and all concerns appropriately addressed, written approval will be provided by the AMEDCC&S. Date of final POI approval will then be entered into the DoD vendor tracking database for administrative and contracting purposes.

## **DOD-CONTRACTED MEDICAL TRAINING INVOLVING USE OF LIVE ANIMALS COMMERCIAL VENDOR REVIEW & APPROVAL PROCESS**

(2) Animal-Use Protocol Administrative Review: Concurrent with POI submission to AMEDDC&S, or upon receipt of written POI approval, contact the Program Manager, U.S. Army Medical Research and Materiel Command Animal Care and Use Review Office (USAMRMC ACURO), (301) 619-6694, to initiate the animal-use protocol administrative review process. The proposed animal-use protocol, along with required support documents, should be submitted to ACURO, via e-mail ([usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil](mailto:usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil)). Upon completion of administrative review, ACURO will provide a list of required and recommended changes, along with items needing additional clarification. Once clarification has been provided, and all required changes made, ACURO will issue approval of the animal-use protocol. Date of final protocol approval will then be entered into the DoD vendor tracking database for administrative and contracting purposes. Following approval, ACURO will get in touch to coordinate scheduling of a compliance inspection.

(3) Compliance Inspection: All documents listed in Enclosure 1 must be submitted to ACURO for administrative review. To initiate the process, contact the Program Manager, USAMRMC ACURO, (301) 619-6694, and coordinate at least *fifteen (15) days prior to the scheduled date of compliance inspection*. Upon completion of inspection, ACURO will provide a detailed report describing results and, if determined favorable, will issue program/site approval. Date of final approval will then be entered into the DoD vendor tracking database for administrative and contracting purposes.

(4) Only after all of the above approvals have been obtained will the vendor then be added to the Army's Approved-Vendor-List (AVL). Once added to the list, vendors are eligible to bid on Army solicitations for contract medical readiness training involving the use of animals. To remain on the list, compliance inspections must be conducted annually, beginning with the date of their initial approval.

### **2. U.S. MARINE CORPS (Conventional Forces)**

#### **A. References**

- (1) Animal Welfare Act, Title 7, U.S. Code, Sections 2131-2158, as amended, and Animal Welfare Act Regulations, Title 9, Code of Federal Regulations, Animals and Animal Products, chapter 1, subchapter A, Animal Welfare, Parts 1-4, as amended.
- (2) DoD Instruction 3216.01, "Use of Animals in DoD Programs", 13 Sep 2010
- (3) DoD Instruction 1322.24, "Medical Readiness Training", 6 Oct 2011
- (4) SECNAVINST 3900.38C, "The Care and Use of Laboratory Animals in DoD Programs", 16 Feb 2005 (*currently undergoing major revision*)
- (5) DoD Component Animal Use Management Plan for the U.S. Navy, 18 Mar 2011
- (6) Marine Corps Combat Development Command (MCCDC) Policy Memorandum, "Combat Trauma Training With Live Tissue Policy Guidance", 1 Jul 2011

#### **B. Instructions for Vendors – Submission, Review, and Approval Process**

(1) Contact the U.S. Marine Corps (USMC) Training and Education Command (TECOM) for USMC specific submission requirements. Point of contact is the Medical Programs Training Officer, [tecom.mtesd.ops@usmc.mil](mailto:tecom.mtesd.ops@usmc.mil), (703) 784-3051. *Ensure all e-mail correspondence contains "MEDPROGTRNGO" in the subject header.* Submit all required documents, as directed, to initiate the review process.

(2) The TECOM point of contact will initiate Program of Instruction (POI) review for subsequent endorsement by the Commanding General, TECOM, and will *concurrently* submit the animal-use protocol, along

## **DOD-CONTRACTED MEDICAL TRAINING INVOLVING USE OF LIVE ANIMALS COMMERCIAL VENDOR REVIEW & APPROVAL PROCESS**

with required program support documents, to the Director of Veterinary Affairs, Department of the Navy, Bureau of Medicine and Surgery (BUMED), for administrative review (see Enclosure 1 for list of required documents).

(3) Upon completion of administrative review, TECOM will provide a list of required and recommended changes, along with items needing additional clarification. Once clarification has been provided, and all required changes made, the POI, the animal-use protocol, and the vendor's Animal Care and Use Program, may then be endorsed for final approval by The Medical Officer of the Marine Corps (TMO). Written approval will be provided by TMO.

(4) Once written approval is provided by TMO, prospective vendors should contact the Director of Veterinary Affairs, BUMED, (301) 619-9241 / [animal.research@med.navy.mil](mailto:animal.research@med.navy.mil), to coordinate and schedule a compliance inspection. Based on results of the inspection, the vendor may be added to the USMC's Approved-Vendor-List (AVL). Once added to the list, vendors are then eligible to bid on USMC solicitations for contract medical readiness training involving the use of animals. To remain on the list, compliance inspections must be conducted annually, beginning with the date of their initial approval.

(5) Upon addition to the USMC's AVL, the Director of Veterinary Affairs, BUMED, will input notice of approval into the DoD tracking database of "approved vendors", including date of POI approval, date of animal-use protocol approval, and date of completion of compliance inspection.

### **3. U.S AIR FORCE (Conventional Forces)**

#### **a. References**

- (1) Animal Welfare Act, Title 7, U.S. Code, Sections 2131-2158, as amended, and Animal Welfare Act Regulations, Title 9, Code of Federal Regulations, Animals and Animal Products, chapter 1, subchapter A, Animal Welfare, Parts 1-4, as amended.
- (2) DoD Instruction 3216.01, "Use of Animals in DoD Programs", 13 Sep 2010
- (3) DoD Instruction 1322.24, "Medical Readiness Training", 6 Oct 2011
- (4) AFMAN 40-401(I), "The Care and Use of Laboratory Animals in DoD Programs", 16 Feb 2005  
(currently undergoing major revision)
- (5) DoD Component Animal Use Management Plan for the U.S. Air Force, 4 Aug 2011

#### **B. Instructions for Vendors – Submission, Review, and Approval Process**

(1) Contact the Chief, U.S. Air Force (USAF) Animal Use Programs, Office of the Surgeon General, (703) 681-8160, for USAF specific submission requirements. Submit required documents, as directed, to initiate the review and approval process (see Enclosure 1 for list of required documents).

(2) The Chief, USAF Animal Use Programs will submit the Program of Instruction (POI) for review and approval by the Surgical Services Consultant, Air Force Medical Operations Agency (AFMOA). Following receipt of POI approval, the Chief, USAF Animal Use Programs will then administratively review the animal-use protocol and animal care and use program documents.

(3) Upon completion of administrative review, the Chief, USAF Animal Use Programs will provide a list of required and recommended changes, along with items needing additional clarification. Once clarification has been provided, and all required changes made, the Chief, USAF Animal Use Programs will issue written notification of animal care and use program and animal-use protocol approval.

## **DOD-CONTRACTED MEDICAL TRAINING INVOLVING USE OF LIVE ANIMALS COMMERCIAL VENDOR REVIEW & APPROVAL PROCESS**

(4) Upon receipt of approval, prospective vendors should contact the Chief, USAF Animal Use Programs, to coordinate and schedule a compliance inspection. Based on results of the inspection, the vendor may then be added to the USAF's Approved-Vendor-List (AVL). Once added to the list, vendors are then eligible to bid on USAF solicitations for contract medical readiness training involving the use of animals. To remain on the list, compliance inspections must be conducted annually, beginning with the date of initial approval.

(5) Upon addition to the USAF's AVL, the Chief, USAF Animal Use Programs, will input notice of approval into the DoD tracking database of "approved vendors", including date of POI approval, date of animal-use protocol approval, and date of completion of compliance inspection.

### **4. U.S. SPECIAL OPERATIONS COMMAND (USSOCOM)(Special Operations Forces, "SOF")**

#### **A. References**

- (1) Animal Welfare Act, Title 7, U.S. Code, Sections 2131-2158, as amended, and Animal Welfare Act Regulations, Title 9, Code of Federal Regulations, Animals and Animal Products, chapter 1, subchapter A, Animal Welfare, Parts 1-4, as amended.
- (2) DoD Instruction 3216.01, "Use of Animals in DoD Programs", 13 Sep 2010
- (3) DoD Instruction 1322.24, "Medical Readiness Training", 6 Oct 2011
- (4) Army Regulation 40-33, "The Care and Use of Laboratory Animals in DoD Programs", 16 Feb 2005 (*currently undergoing major revision*)
- (5) DoD Component Animal Use Management Plan for the USSOCOM, 11 Apr 2011
- (6) USSOCOM Directive 350-29cc, "Special Operations Forces (SOF) Baseline Interoperable Medical Training Standards", 7 Sep 2012

#### **B. Instructions for Vendors – Submission, Review, and Approval Process**

- (1) *Prior to seeking USSOCOM approval*, vendors must first have current animal-use protocol approval, and documentation of favorable results of site inspection within the past 12 months, from at least one of the Military Services (U.S. Army, U.S. Marine Corps, or U.S. Air Force). See Enclosure 2.
- (2) After receiving final approval from at least one of the Military Services as noted above, vendors must then meet additional USSOCOM specific requirements. Contact the Command Veterinarian, USSOCOM SOCS-SG-VET, 7701 Tampa Point Boulevard, MacDill AFB, FL 33621-5323, email: [SOCOMVET@socom.mil](mailto:SOCOMVET@socom.mil), for specific requirements and POI submission instructions. See Enclosure 3.
- (3) USSOCOM will provide written notification of vendor approval once all administrative requirements are met. Vendors are then eligible to bid on USSOCOM contract solicitations for medical training involving the use of animals. **NOTE:** USSOCOM approval is Service Component specific.
- (4) After being added to USSOCOM's AVL, the Command Veterinarian will input notice of approval into the DoD tracking database of "approved vendors", including date of POI approval.

### **5. ADMINISTRATIVE RECIPROCITY**

Per DoD Instruction 3216.01, all Component Animal Use Oversight offices (U.S. Army, U.S. Navy, U.S. Air Force, and USSOCOM) have established administrative reciprocity and therefore *may* accept animal-use protocol approvals and results of site inspections, initial, annual, or otherwise, when provided by one another. Approvals

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obtained from one office will be provided, as applicable, to other offices, to facilitate the review and approval process and preclude redundancy of effort. Each respective Component office, however, reserves the right to conduct Component-specific administrative reviews, site inspections, or request additional information at any time as deemed necessary. It should additionally be noted that once "approved vendor" status has been granted by one Component, such status does not automatically confer to other Components. In order to compete for a Component-specific contract, vendors *must first* be included on the AVL for that particular Component. All DoD and Component-specific requirements must be met in order to obtain "approved vendor" status. To remain on the list, compliance inspections must be conducted annually, beginning with the date of initial approval. Similar reciprocity has not been established for POI review and approval.

### **6. ADDITIONAL ADMINISTRATIVE REQUIREMENTS**

A. Animal Use-Protocol. Animal-use protocol approvals are valid for three (3) years from date of initial approval by the vendor's IACUC. At that time protocols are considered expired and any previously approved activities involving the use of animals must cease immediately. Such activities should not occur beyond the specific date of protocol expiration, regardless of any existing government contracts. To preclude potential interruption or cancellation of planned training events, an updated protocol, to include new literature searches, should be submitted to the respective Component Animal Use Oversight office at least 60-90 days prior to the protocol expiration date. Vendors unable to meet this requirement will be removed from all Component AVL's on the date of protocol expiration. **NOTE:** *All* amendments or modifications to the IACUC-approved protocol *must* be reviewed and approved by the vendor's IACUC, and subsequently by the respective Component Animal Use Oversight office, prior to any such changes being implemented. Any changes implemented without obtaining prior approval will be considered non-compliance and may result in immediate suspension of training activities involving animals.

B. Compliance Inspections. Per DoD Instruction 3216.01, results of compliance inspections are valid for a period of one (1) year from the date of initial completion. Thereafter, to remain on the AVL, inspections must be completed annually, beginning with the date of initial approval. It is advisable for inspections to be coordinated and scheduled with the respective Component Animal Use Oversight office at least 60-90 days prior to the annual date of expiration. Advanced coordination will help facilitate the review and approval process and preclude potential interruption or cancellation of planned training events. Vendors unable to meet this requirement will be removed from all Component AVL's on the date of inspection expiration.

C. Program of Instruction. POI approvals are Component and course specific and are considered valid as follows: U.S. Army and USAF – for a period of three (3) years from the date of initial approval, or until the expiration date of the corresponding animal-use protocol, whichever comes first; USMC – for a period of two (2) years from the date of initial approval, or until the expiration date of the corresponding animal-use protocol, whichever comes first; USSOCOM – for a period of one (1) year, or until the expiration date of the corresponding animal-use protocol, whichever comes first. At all such dates specified, POIs are considered expired and any previously approved instructional material must be reapproved, by each applicable Service/Component, prior to the continued conduct of any medical training, whether planned instruction or activities involve the use of animals or not, and regardless of any existing government contracts. To preclude potential interruption or cancellation of planned training events, an updated POI should be submitted, according to the above Service/Component specific instructions, at least 90-120 days prior to the POI or animal-use protocol expiration date. It is essential that re-approval(s) be obtained for *each* supported Service/Component (U.S. Army, U.S. Marine Corps, U.S. Air Force, or USSOCOM). Service/Component POI approval times may significantly vary depending on mission priorities and current workload. At this time, reciprocity for POI approval has not been established between Services/Components. Vendors unable to meet this requirement will be removed from all applicable Component-specific AVL's on the POI (or animal-use protocol) expiration date, whichever comes first.

D. Additional requirements may be needed as specified in DoD and Service/Component policies, government solicitations and contracts, or as deemed necessary by Component Animal Use Oversight offices.

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### **Enclosure 1 Animal-Use Protocol and Program Review Documents**

The following documents are required in your submission packet to initiate the animal-use protocol or compliance inspection. Additional information may be required and will be requested as deemed necessary. Submission guidance may be obtained from the respective Component Animal Use Oversight office.

1. Vendor's IACUC-approved version of the animal-use protocol, preferably in DoD standardized format. The standardized protocol template may be found in reference (4) or obtained by contacting any one of the Component Animal Use Oversight offices. Detailed instructions for completion are also provided in reference (4). **NOTE:** Although the DoD standardized template is not required, all requested information contained therein must be appropriately addressed, in sufficient detail, and included with submission of the IACUC-approved protocol.
2. Vendor's IACUC approval memo for the above animal-use protocol. **NOTE:** All amendments or modifications to the IACUC-approved protocol must be reviewed and approved by the vendor's IACUC, and subsequently by the respective Component Animal Use Oversight office, prior to any such changes being implemented. Any changes implemented without obtaining prior approval will be considered non-compliance and may result in immediate suspension of animal-use activities.
3. Documentation of continuing review of the above approved protocol by the vendor's IACUC. **NOTE:** Continuing reviews must be conducted by the vendor's IACUC at least annually.
4. When medical training involving the use of live animals is to be conducted within the U.S., provide a written statement indicating that animals will be or have been legally obtained from suppliers licensed by the USDA in accordance with sections 2133-2134 of reference (1), unless the supplier claims to meet established exemption criteria. If claiming exemption, provide the applicable documentation. When training is to be conducted outside of the U.S., provide a written statement indicating that animals will be or have been legally obtained from suppliers in accordance with current national policy of the applicable Host Nation.
5. Most recent USDA inspection report, unless vendor is exempt from inspection. All USDA inspection reports received during the period of the contract should be immediately submitted to the respective Component Animal Use Oversight office. **NOTE:** If a vendor is ever notified by the USDA that their Animal Care & Use Program is under investigation, such notification should be provided to all Component Animal Use Oversight offices within five (5) business days of receiving the notice. Any adverse event(s) having potential to impact DoD continued support of a government contract, regardless if subject to USDA investigation or not, should be immediately reported to the respective Component Animal Use Oversight office.
6. Two (2) most recent results of vendor IACUC's semi-annual program review and facility inspection, including the follow-up report provided to the Institutional Official (IO) signed by a majority of IACUC members. **NOTE:** Semi-annual program review and facility inspections must be conducted by the vendor's IACUC at least once every six (6) months.
7. Current IACUC membership roster. If the vendor's Chief Executive Officer (CEO) has granted delegated authority to the IO, such delegation should be specific and in writing. Provide documentation if applicable.
8. Minutes of the last three (3) IACUC meetings documenting member attendance and committee deliberations.
9. Documentation of training that all IACUC members have completed over the course of the past year in order to meet mandated training requirements as specified in references (1) and (2).
10. Current list of all IACUC policies and/or standard operating procedures (SOPs), including committee review, approval, and revision dates.
11. Emergency Preparedness and Response plan that includes disposition of animals.

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12. Detailed description, policy, or SOP of vendor's Occupational Health and Safety Program.
13. IACUC policy or SOP for the reporting of animal welfare concerns. In addition, provide copies of any final reports of non-compliant issues identified within the past year requiring notification to AAALAC, USDA, or any of the DoD Component Animal Use Oversight offices. **NOTE:** Any animal welfare concern(s) having potential to impact DoD continued support of a government contract should be immediately reported to the respective Component Animal Use Oversight office.
14. Most recent correspondence with AAALAC indicating current accreditation status. **NOTE:** If a vendor is ever notified by AAALAC of loss of program full accreditation, notification should be provided to the respective Component Animal Use Oversight office within five (5) business days.
15. Documentation of current registration with the USDA, unless exempt.
16. Most recent USDA Annual Report of Research Facility (APHIS Form 7023). **NOTE:** Annual reports should be submitted to the respective Component Animal Use Oversight office for the duration of any existing contract.
17. Documentation of current registration with the Drug Enforcement Administration (DEA).
18. Documentation of current veterinary licensure for the state/location where training is to be conducted.
19. IACUC policy or SOP on the appropriate supervision and use of DEA-regulated or controlled substances.
20. Current approved version of vendor's Program of Instruction (POI) with applicable Component-specific approval memo(s).

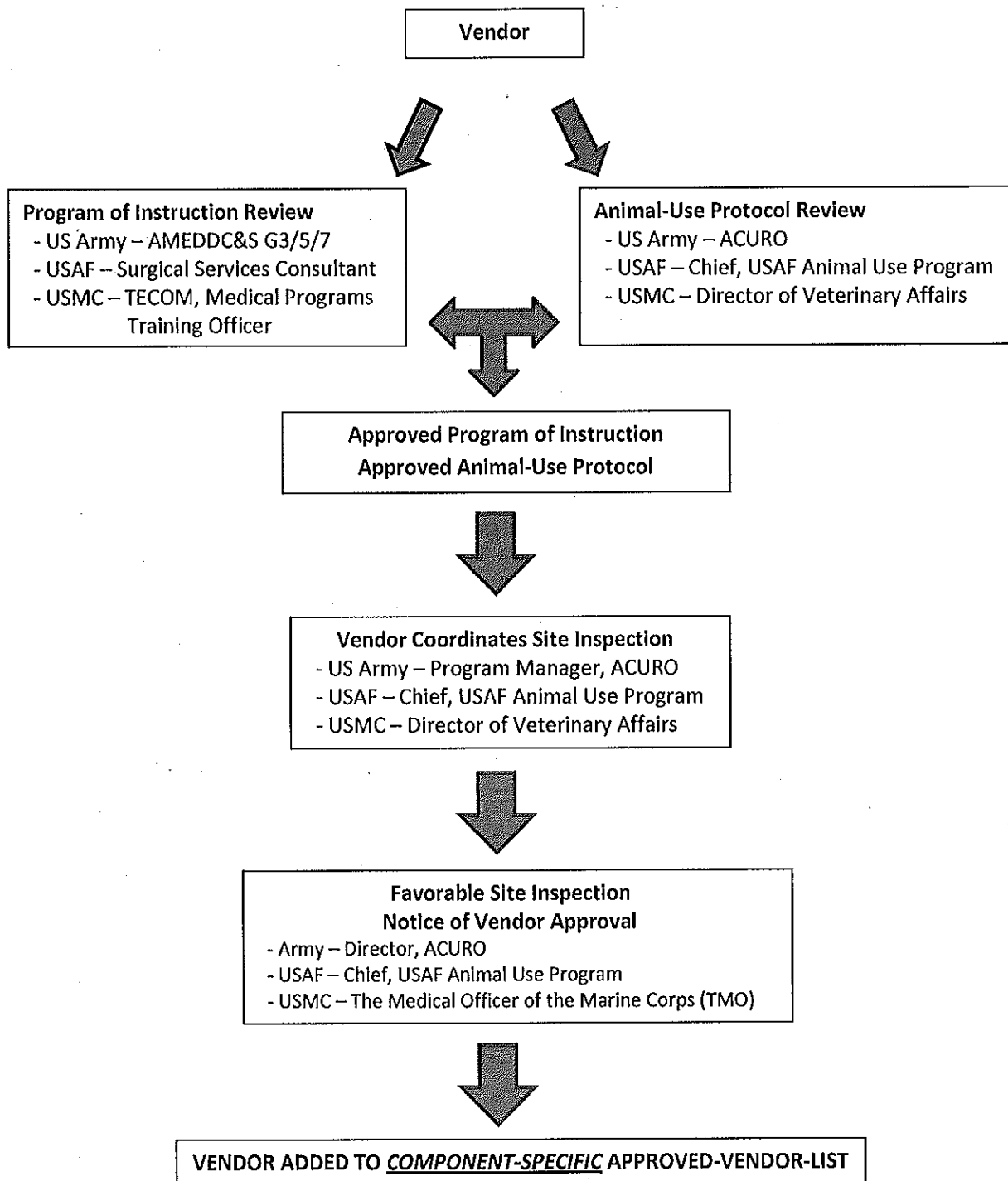
The following website may be used as a convenient method for sending the above listed information:  
<https://safe.amrdec.army.mil/safe2/>. Submission of all documents, however, should be as specifically directed above. AMRDEC's Safe Access File Exchange (SAFE) is an alternative program that allows for the secure transmission of much larger files (up to 2GB) than can normally be sent via regular e-mail. It permits encryption, is CAC-enabled, and allows for the creation of \*.zip files. It does not fill up the recipient's inbox and can mark files "FOUO" or as "Privacy Act" data.



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**Enclosure 2**

**(U.S. Army, U.S. Air Force, U.S. Marine Corps)**



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**Enclosure 3**

**U.S. Special Operations Command (USSOCOM)**

